

### **REMARKS**

Claims 13-16 and 19-24 are pending. Claims 1-12 and 17-18 have been deleted without disclaimer or prejudice. Claims 19-24 have been newly added.

An Interview was conducted with the Examiner on May 20, 2008, discussing entry of an after-final amendment and submission of a § 1.132 declaration supporting the scope of the amended claims. Applicants thank the Examiner for her time.

Claims 13 and 14 have been amended to incorporate the term “prophylactically”, “viruses” and “SEQ ID NO.’s 7, 9 and 18”. Support is found in the specification at ¶’s [0018] and [0084] for “prophylactically” and in the claim themselves for the remaining terms. Claim 15 now only recites “viruses”. Claim 16 has been amended to replace “the” with “an”. New claims 19-24 cover parasitic organisms. Support for claims 19-24 can be found at ¶ [0007]. Since the subject matter of the amendments has already been searched and considered, or alternatively indicated by the Examiner as fairly being encompassed by the previously pending claims, entry and consideration is requested. No new matter has been added.

The specification at ¶ [0012] has been amended to conform with the “Sequence Listing” of 12/23/05 to indicate that X is Ala or Asp and when X is Ala, then Ala is either cyclohexylalanine or D-alanine. Also, ¶ [0012] has been amended to include a comma between acetyl and ClAc in ¶ [0012] to recite “acetyl, ClAc and BrAc”. No new matter has been added.

The Sequence Listing has been amended so that SEQ ID NO. 6 has two Glu residues (EE). Support is found in the specification at ¶ [0057]. As for Office Action assertion that the Sequence Listing should be amended to recite “acetylaspartate, propionylaspartate,

bromoacetylaspartate, or chloroacetylaspartate” at position 1, it is believed that the Sequence Listing already adequately recites these features as MISC\_FEATURE’s, which recite acetyl, ClAc (chloroacetic acid), and BrAc (bromoacetic acid) where Asp is the optional amino acid at position 1. SEQ ID NO. 9 has been amended to delete Lysine and Phenylalanine from Xaa in position 6. The amendment to the paper copy of the "Sequence Listing" is submitted herein under § 1.825(a) by the submission of substitute sheets as an Appendix A. The substitute sheets include no new matter. As required under § 1.825(c), a substitute copy of the computer readable form (CRF) is also submitted whereby under Patent EBC, FAQ p220efs191, a “Sequence Listing” filed in text form through electronic filing will be accepted as the CRF of the “Sequence Listing”. The CRF is the same as the substitute copy of the "Sequence Listing."

A § 1.132 declaration is submitted supporting the scope of the pending claims.

1. **Rejection of Claims 13-17 under 35 U.S.C. § 112, ¶ 1 (enablement)**

The Office Action maintained the rejection because the specification allegedly fails to provide enablement for a method for treating infections and conditions. The rejection is traversed because presently pending independent claim 13 recites a method for treating infectious conditions caused by viruses comprising prophylactically administering a polypeptide as shown in SEQ ID NO.'s 7, 9 and 18 to an animal in need thereof. Additionally, a § 1.132 declaration is submitted establishing effectiveness against additional viruses and *Leishmania*.

2. **Double Patenting Rejections**

The Examiner maintained the rejection over copending Application No. 11/696,124. Insofar as this application is no longer pending, the rejection is moot.

The Examiner maintained the rejection over U.S. Patent No. 6,572,860 in view of WO 01/89286. The rejection is traversed because the examined application claims are neither anticipated by, nor would have been obvious over the reference claim. See In re Berg, 46 USPQ2d 1226 (Fed. Cir. 1998). In particular, claim 6 of the cited patent recites a method for the treatment of herpes simplex virus using a conjugated polypeptide according to claim 1, which is recited as being “an immunogenic conjugated polypeptide effective as immunogen in a vaccine for treatment or prevention of infection by herpes simplex virus, said polypeptide represented by the formula  $P_1\text{-x-P}_2$  or  $P_2\text{-x-P}_1$  where  $P_1$  represents a herpes simplex virus specific antigenic peptide from a protein of herpes simplex virus type 1 or type 2, selected from the group consisting of *ICP27*, *glycoprotein B*, *ribonucleotide reductase*, *ICP4*, *ICP34.5*, *glycoprotein E* and *glycoprotein F*; and  $P_2$  represents an immunomodulatory peptide which is a portion of an immunoprotein which promotes binding to a class or subclass of T cells and which direct a predominantly TH1 type immune response to the peptide  $P_1$ ”. In contrast, the presently claimed SEQ ID NO.’s 7, 9 and 18 do not contain the formula  $P_1\text{-x-P}_2$ . Specifically, the claimed SEQ ID NO.’s 7, 9 and 18 do not contain a  $P_1$  portion containing a herpes simplex virus specific antigenic peptide from a protein of herpes simplex virus type 1 or type 2, selected from the group consisting of *ICP27*, *glycoprotein B*, *ribonucleotide reductase*, *ICP4*, *ICP34.5*, *glycoprotein E* and *glycoprotein F* or a linker x. The presently pending claims 13-15 are patentably distinct from claim 6 of the cited patent for at least these reasons.

The Examiner maintained the rejection over U.S. Patent No. 6,951,647. The rejection is traversed because the examined application claims are neither anticipated nor obvious over the

reference claim(s). In the present case, claim 7 of the cited patent recites a method of eliciting a cellular immune response in a human patient in need thereof, comprising administering to said patient an immunologically effective amount of the peptide construct of claim 2 or 3, which is claimed as a *first* T cell specific binding peptide and a *second* T cell specific binding peptide, said first and second peptides being derived from different molecules and covalently linked together. In contrast, the presently claimed SEQ ID NO.'s 7, 9 and 18 do not contain a separate first T cell specific binding peptide and a second T cell specific binding peptide. The presently pending claims 13-15 are patentably distinct over claim 7 of the cited patent for at least these reasons.

In light of the foregoing, the application is now in condition for allowance. It is therefore respectfully requested that the rejection(s) be withdrawn and the application passed to issue.

Respectfully submitted,  
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